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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Agency for Healthcare Research and Quality
Agency Information Collection Activities:
Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Development of a Health Information Rating System (HIRS)." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by (insert date 60 days after date of publication).

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Development of a Health Information Rating System (HIRS)

Over the past several years, limited health literacy has been identified as an important health care quality issue. Healthy People 2010 defined health literacy as 'the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions'. In 2003, the Institute of Medicine identified health literacy

as a cross-cutting area for health care quality improvement. According to the 2003 National Assessment of Adult Literacy, only 12 percent of adults have proficient health literacy.

Persons with limited health literacy face numerous health care challenges. They often have a poor understanding of basic medical vocabulary and health care concepts. A study of patients in a large public hospital showed that 26 percent did not understand when their next appointment was scheduled and 42 percent did not understand instructions to "take medication on an empty stomach." In addition, limited health literacy leads to more medication errors, more and longer hospital stays, and a generally higher level of illness.

Health care providers can improve their patients' health outcomes by delivering the right information at the right time in the right way to help patients prevent or manage chronic conditions such as diabetes, cardiovascular disease, hypertension, and asthma. Electronic health records (EHRs) can help providers offer patients the right information at the right time during office visits, by directly connecting patients to helpful resources on treatment and self-management. EHRs can also facilitate clinicians' use of patient health education materials in the clinical encounter. However, health education materials delivered by EHRs, when available, are rarely written in a way that is understandable and actionable for patients with basic or below basic health literacy – an estimated 77 million people in the United States.

In order to fulfill the promise of EHRs for all patients, especially for persons with limited health literacy, clinicians should have a method to determine how easy a health education material is for patients to understand and act on, have access to a library of easy-to-understand and actionable materials, understand the relevant capabilities and features of EHRs to provide effective patient education, and be made aware of these resources and information. Therefore, AHRQ developed a task order that resulted in contract #HHSA290200900012I to complete the following four major tasks: 1) develop a valid and reliable Health Information Rating System (HIRS), 2) create a library of patient health education materials, 3) review EHR's patient education capabilities and features, and 4) educate EHR vendors and users. This information collection project relates to the first task only.

The goal of this information collection project is to develop a valid and reliable Health Information Rating System (HIRS). The HIRS will offer a systematic method to evaluate and compare the understandability and actionability of health education materials. Health education materials are understandable when consumers of diverse backgrounds and varying degrees of health literacy can process and explain key messages. Health education materials are actionable when consumers of diverse backgrounds and varying levels of health literacy can identify what they can do based on the information presented.

A Draft HIRS has been developed through a rigorous multi-stage approach and draws upon existing rating systems, the evidence base in the literature, and the real-world expertise and experience of a Technical Expert Panel (TEP). The final stage of developing a reliable and valid rating system to assess the understandability and actionability of patient health education materials is

testing with consumers. AHRQ is following a 5-step process to develop a valid and reliable HIRS:

- 1) Gather and synthesize evidence on existing rating systems and literature on consumers' understanding of health information. Seek TEP review of the summary of existing health information rating systems. Develop item pool for each domain (i.e., understandability and actionability).
- 2) Assess the face and content validity of the domains (i.e., understandability and actionability) with the TEP.
- 3) Assess the inter-rater reliability of the HIRS on 16 different health education materials (8 English-language materials and 8 Spanish-language materials) using a total of 8 raters — 4 raters per material. Seek TEP review of results and provide guidance on how to address discrepancies.
- 4) Assess the construct validity of the HIRS by conducting testing with 48 consumers — 24 English-speaking and 24 Spanish-speaking consumers. Consumers will review materials and be asked questions to test whether they understand the materials and whether they know what actions to take.
- 5) Finalize the HIRS and instructions for users, and make them publicly available on AHRQ's website.

Steps 1, 2 and 3 do not involve data collections requiring OMB approval and have already been completed.

This study is being conducted by AHRQ through its contractor, Abt Associates, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a) (1) and (2).

Method of Collection

To complete steps 4 and 5 the following data collections and activities will be implemented:

- 1) Demographic Questionnaire -- The demographic questionnaire will collect basic demographic information about each consumer participant. This data will allow the analysis to detect differences in health literacy by population subgroups.
- 2) Short Test of Functional Health Literacy in Adults (S-TOFHLA) Questionnaire -- The S-TOFHLA will be administered to all participants to assess their level of health literacy.
- 3) Health Education Materials & Interview - English, Inhaler --Each English-speaking participant will be randomly assigned one of a set of three materials on using asthma inhalers, which include: 1) a video entitled "How to Use an Inhaler," by the American College of Physicians Foundation, 2) a material accessed via the internet entitled "Inhaled Asthma Medications: Tips to Remember," by the American Academy of Allergy, Asthma & Immunology, and 3) a

material accessed via the internet entitled "How to Use Your Metered-Dose Inhaler the Right Way," by the McKinley Health Center. After seeing the video or reading the randomly assigned material, a brief interview will be conducted to assess the participants' understanding of how to use an inhaler and what actions to take based on the material.

4) Health Education Materials & Interview - English, Colonoscopy - Each English-speaking participant will be randomly assigned one of a set of three materials about colonoscopy, which include: 1) a video entitled "Colonoscopy," by Medline Plus, 2) a pdf material accessed via the internet entitled "Colonoscopy," by the American College of Surgeons and 3) a material accessed via the internet entitled, "Colonoscopy," by Jackson Siegelbaum Gastroenterology. After seeing the video or reading the randomly assigned material, a brief interview will be conducted to assess the participants' understanding of the colonoscopy procedure and what actions to take based on the material.

5) Health Education Materials & Interview - Spanish, High Blood Pressure - Each Spanish-speaking participant will be randomly assigned one of a set of three materials about high blood pressure, which include: 1) a video entitled "Hipertension esencial," by Medline Plus, 2) a website material accessed via the internet entitled "¿Que es la presión arterial alta?," by the National Heart Lung and Blood Institute (NHLBI) and 3) a pdf material accessed via the internet entitled, "Presion Sanguinea Alta," by the National Center for Farmworker Health. After seeing the video or reading the randomly assigned material, a brief interview will be conducted to assess the participants' understanding of high blood pressure and what actions to take based on the material.

6) Health Education Materials & Interview - Spanish, Colonoscopy - Each Spanish-speaking participant will be randomly assigned one of a set of three materials about colonoscopy, which include: 1) a video entitled "Colonoscopia," Main Line Health, 2) a pdf material accessed via the internet entitled "Colonoscopia: Lo Que Usted Debe Saber," by the Nebraska Department of Health and Human Services (DHHS) and 3) a material accessed via the internet entitled, "Colonoscopia," by Centro Medicao ABC. After seeing the video or reading the randomly assigned material, a brief interview will be conducted to assess the participants' understanding of the colonoscopy procedure and what actions to take based on the material.

The data collected from this project will be used to assess the construct validity of and inform revisions to the HIRS. The HIRS will be the first system that can assess the understandability and actionability of patient health education materials that can be incorporated into an EHR, including print and multimedia materials. Note that the materials to be assessed need not currently be incorporated into EHRs; for now, AHRQ is focusing on materials that have the potential to be incorporated into EHRs.

No claim is made that the results from this study will be generalizable in the statistical sense. Rather, the consumer testing will be informative and critical to ensuring we have developed a valid rating system by conducting consumer testing.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the annualized burden hours for the respondents' time to participate in this research. The Demographic and S-TOFHLA questionnaires will be completed by all 48 participants and takes 5 and 7 minutes, respectively, to complete. Each of the 48 participants will review 2 different sets of health education materials and then participate in a short interview for each material topic. English-speaking participants will review materials related to inhaler use and colonoscopy while Spanish-speaking participants will review materials related to high blood pressure and colonoscopy. To review each material and participate in the associated interview requires 30 minutes (15 minutes to review the materials and 15 minutes for the interview). The total annualized burden is estimated to be 58 hours.

Exhibit 2 presents the estimated annualized cost burden associated with the respondents' time to participate in this research. The total cost burden is estimated at \$962.

Exhibit 1. Estimated annualized burden hours

Data Collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Demographic Questionnaire	48	1	5/60	4
S-TOFHLA Questionnaire	48	1	7/60	6
Health Education Materials & Interview - English, Inhaler	24	1	30/60	12
Health Education Materials & Interview – English & Spanish, Colonoscopy	48	1	30/60	24
Health Education Materials & Interview - Spanish, High Blood Pressure	24	1	30/60	12
Total	192	na	na	58

Exhibit 2. Estimated annualized cost burden

Data Collection	Number of respondents	Total burden hours	Average hourly wage rate*	Total cost burden
Demographic Questionnaire	48	4	\$21.35	\$85
S-TOFHLA Questionnaire	48	6	\$21.35	\$128

Health Education Materials & Interview - English, Inhaler	24	12	\$21.35	\$256
Health Education Materials & Interview - English & Spanish, Colonoscopy	48	24	\$21.35	\$512
Health Education Materials & Interview - Spanish, High Blood Pressure	24	12	\$21.35	\$256
Total	192	58	na	\$1,237

* Based upon the mean wage for all occupations, National Compensation Survey: Occupational wages in the United States May 2010, "U.S. Department of Labor, Bureau of Labor Statistics."

Estimated Annual Costs to the Federal Government

The total cost of this contract to the government is \$524,945, and the project extends over 3 years (July 19, 2010 to July 18, 2013). The data collection for which we are seeking OMB clearance will take place from September 1, 2012 to December 31, 2012. Exhibit 3 shows a breakdown of the total cost as well as the annualized cost for the data collection, processing and analysis activity for this entire contract.

Exhibit 3. Estimated Cost

Cost Component	Total Cost	Annual Cost
Project Development	\$66,447	\$22,149
Data Collection Activities	\$129,547	\$43,182
Data Processing and Analysis	\$129,548	\$43,183
Publication of Results	\$131,571	\$43,857
Project Management	\$67,832	\$22,611
Total	\$524,945	\$174,982

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed

collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 22, 2012

Carolyn M. Clancy,
Director

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